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March 23, 2011

BY ECF & HAND DELIVERY

The Honorable Stanley R. Chesler
United States District Judge
United States Post Office and Courthouse Building
Newark, New Jersey 07101

Re: *In re Merck & Co., Inc. Securities, Derivative and "ERISA" Litigation*,
MDL No. 1658 –
This Document Relates To: The Consolidated Securities Action, Civil Action
Nos. 05-1151(SRC)(MF); 05-2367(SRC)(MF)

Dear Judge Chesler:

We write to draw the Court's attention to the Supreme Court's unanimous decision yesterday in *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156, 2011 WL 977060, 563 U.S. ____ (March 22, 2011) (copy attached as Ex. A), which expressly rejected two primary arguments that Merck and the Individual Defendants rely upon in their pending motions to dismiss in this case.

First, Defendants here assert that none of their statements concerning Vioxx's safety or commercial prospects were materially false or misleading because none of the adverse information they omitted to disclose "would [have] establish[ed] a definitive link between Vioxx and increased cardiovascular risk." Merck Defendants' Opening Brief (Dkt. No. 254-1) at 56. In particular, relying on *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000), Defendants assert that any adverse information about Vioxx's safety that did not establish a statistically significant cause and effect relationship between Vioxx and adverse health effects was necessarily immaterial as a matter of law. *Id.*

In *Matrixx*, however, the Supreme Court expressly rejected the argument that adverse information relating to a drug's safety must rise to the level of statistical significance in order to be material, explaining that such a "categorical rule would artificially exclude information that would otherwise be considered significant to the trading decision of a reasonable investor." *Id.*

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at 11 (internal quotation marks omitted). Noting that “medical professionals and regulators act on the basis of evidence of causation that is not statistically significant,” the Court held that “it stands to reason that in certain cases investors would as well.” *Id.* at 15. The Court further reiterated that the materiality inquiry is “fact-specific” and takes into consideration the “source, content, and context” of the undisclosed information (*id.*), and reaffirmed that the relevant question on a motion to dismiss is whether, under Rule 8(a), a complaint “plausibly alleges” (*id.* at 17, n.12) that “a reasonable investor would have viewed the nondisclosed information as having significantly altered the ‘total mix’ of information made available.” *Id.* at 15-16 (citations omitted).

Applying this analysis to the facts in *Matrixx*, the Supreme Court held that the plaintiffs had adequately pled materiality because they alleged the existence of undisclosed information indicative of a “plausible causal relationship” between (a) the drug at issue and (b) an adverse effect that posed “a significant risk to the commercial viability” of that drug (which, as here, was one of the defendant company’s most important products). *Matrixx* at 18-19. For these same reasons, the omitted information concerning the risk that Vioxx caused cardiovascular events, as alleged in the Complaint, was also plainly material.¹

Second, *Matrixx* held that the scienter allegations in that case – that *Matrixx*: (1) was so concerned about the drug’s potential side effects that it undertook a number of measures to investigate the threat; (2) successfully prevented a physician from using the company’s name in a presentation concerning the link between the drug and the adverse effect; and (3) issued a misleading press release suggesting that prior studies had confirmed that the drug did not cause the adverse side effect – plainly supported a strong inference of scienter. *See Matrixx* at 21. Indeed, the Supreme Court found that “the inference that *Matrixx* acted recklessly (or intentionally, for that matter) is at least as compelling, if not more compelling, than the inference that it simply thought the reports did not indicate anything meaningful about adverse effects.” *Id.*

Here, as in *Matrixx*, the Complaint alleges numerous specific facts demonstrating, *inter alia*, that Merck: (1) had “great concern” arising from even before the start of the Class Period that Vioxx’s adverse cardiovascular effects would “kill the drug,” and undertook various measures to investigate, and then conceal, the threat (¶¶102-22); (2) pressured and intimidated members of the medical community who questioned the safety of Vioxx (¶¶384-85); and (3) issued affirmatively false statements that, aside from VIGOR, there was “no indication” from Merck’s prior studies, other internal data, or its post-marketing experience with Vioxx that Vioxx might be prothrombotic. *See, e.g.*, ¶¶147-48, 150, 154, 159.²

¹ Of course, for the reasons discussed in Plaintiffs’ Opposition Brief (Dkt. No. 262) at 39-42, Plaintiffs’ materiality allegations would also have satisfied even the Third Circuit’s more stringent *Oran v. Stafford* standard, which has now been effectively overturned by *Matrixx*.

² All “¶” citations are to the Corrected Consolidated Fifth Amended Class Action Complaint, Dkt. No. 231.

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Further, in addition to the indicia of scienter here that was held to be sufficient in *Matrixx*, the allegations of scienter in this matter go even further because the Complaint *also* (i) identifies internal Merck email confirming defendants' belief that VIOXX was prothrombotic (*e.g.* ¶138); (ii) alleges how Merck intentionally designed its own clinical trials to avoid generating adverse data (*e.g.*, ¶¶127-29, 134); and (iii) even alleges how Merck actually manipulated statistically significant adverse clinical trial data, in breach of medical ethics, so that the data would *appear* to be insignificant, all as part of their efforts to conceal Vioxx's dangers and protect Merck's "blockbuster" franchise. *See, e.g.*, ¶¶167-68, 177-83. For these reasons, Plaintiffs' Complaint far exceeds the allegations necessary to meet the scienter pleading requirement under *Matrixx*.

Respectfully submitted,

CARELLA, BYRNE, CECCHI,
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/s/ James E. Cecchi

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cc: All Counsel (via ECF)